

**DISCUSSION OF THE AMENDMENT****Rejection under 35 USC 112**

Applicant has amended the claims to address those rejections on the grounds. Specifically, applicant has removed reference to "broad spectrum" from the independent claim to avoid confusion that all compounds are all equally as effective on all microbes. Applicant has read and considered the rejections under 35 USC 112 related the undue experimentation rejection and in light of the above requests the rejection be withdrawn. Applicant has also corrected the rejection to the "." In claim one instead of the ",".

Applicant points out the following:

**[071] Applications Results**

<u>SAMPLE</u>	<u>Sa</u>	<u>Psa</u>	<u>Ca</u>	<u>An</u>	<u>Score</u>	<u>Comments</u>
Applications Example 1	2	8	3	6	19	Good on gram negative, gram positive, yeast and mold
Applications Example 2	1	2	3	8	14	Good on Bacterial and Yeast No Mold Activity
Applications Example 3	1	2	1	2	6	Excellent Activity overall

The fact that some compounds show a grater affinity for one type of microbe over another does not make the use of the compounds as antimicrobials inoperative. When the compounds of the present invention are used they are antimicrobials. It is much like being pregnant, either you are or you are not. There is always a degree of interest in optimizing the specific product chosen in all antimicrobial. This is true not only of antimicrobials but of every chemical. Chemicals vary from other related chemicals as to degree of a specific property but still have that property. This is even more relevant to antimicrobials. It is well known that when bacteria taken from a patient is tested it is tested against a number of antimicrobials to determine the optimum effectiveness. The testing is called commonly culture and sensitivity. This test clearly points out that technology in the antimicrobial art allows for variability in performance of well accepted prescription antibiotics. The differences in effectiveness of antimicrobials vary based upon the specific genus and species tested, but all are prescription antibiotics certified to be effective. This having been said the compounds tested in the laboratory are all antimicrobial; the difference in degree is mote. Clearly, it cannot be said that the applicant has an obligation to test every specific genus, species and subspecies of all microbes and direct claims to each organism. Applicant respectfully contends that it has been shown that the compounds of the present invention are anti-microbials.

The fact that the art is silent in the predictability of the antimicrobial activity of the current compositions speaks to the patentability of the current invention and is the reason why the compositions should be allowed.

The assertion that there has not been given enough information on test methodology is likewise traversed as it imposes on the applicant an arbitrary requirement

to pick a test that is pleasing to one and not another. This too places a burden on the applicant to run all tests and offer them for review. Applicant has presented enough data to allow one of ordinary skill in the art to use the process of the current invention.

Applicant states:

[068] The antimicrobial compounds described above have activity against bacteria, yeasts and molds when employed at appropriate levels of concentration and may be used to inhibit growth or effectively destroy these organisms. It should be obvious that the required effective concentration or amount will vary with particular organisms and also on a number of other factors in particular applications. In general, however, effective antimicrobial response is obtained when the active agent is employed in concentrations ranging between 5 and 10,000 ppm (parts per million) and preferably between about 50 and 1,000 ppm. Generally, the concentration of the agent required for bactericidal activity will be lower than the concentration required for fungicidal activity. (Emphasis added)

Applicant also states:

"A study was conducted by Bio-Control Consultants Inc. 43 Mohican Drive Westfield N.J. 07090. The purpose was to determine the antimicrobial capability of the compounds of the present invention (alkylpolyglucoside quats) utilizing the zone inhibition technique. The test materials were evaluated for gross antimicrobial activity against a series of four (4) test organisms: *Pseudomonas aeruginosa* (Gram negative bacteria); *Staphylococcus aureus* (Gram positive bacteria); *Candida albicans* (yeast) and

*Aspergillus niger* (mold) utilizing the zone inhibition technique. Results of the assays are presented below.

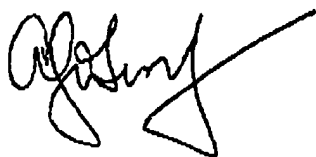
Agar was prepared and inoculated with the test organism, then poured into a plate. The examples chosen were diluted to 0.1, 0.2 and 0.4 and applied to a cellulose disc, and allowed to dry. The dry cellulose disc was applied to the hard agar and the agar was placed in an incubator to allow the organisms to grow."

This test was conducted by an outside laboratory expert in these matters and conclusions were drawn by these experts. The methodology was chosen by impartial experts and applicant respectfully contends is beyond reproach.

Applicant respectfully contends that "The quantity of experimentation needed to make and use the invention based upon the content of the disclosure is too large" is unsupportable. Applicant has already stated that all compounds tested are antimicrobials and that using them as indicated will provide antimicrobial effects.

Applicant respectfully requests reconsideration of the pending claims as amended and anxiously awaits an early *Notice of Allowance* on the now pending claims.

Respectfully submitted



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